Janssen and Gilead Amend Single-Pill HIV Regimen Collaborations

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Janssen and Gilead Sciences have announced amendments to ongoing collaborations to develop single-tablet regimens (STRs) to treat HIV. The STRs include one based on Tybost (cobicistat)-boosted Prezista (darunavir) and another that is an updated version of Complera (rilpivirine/tenofovir disoproxil fumarate (TDF)/emtricitabine).

Amending an agreement between the two companies that was established in 2011, Janssen has pledged to conduct all further clinical development of the STR of Janssen's Prezista and Gilead's Tybost, Emtriva (emtricitabine) and the investigatory tenofovir alafenamide fumarate (TAF), an updated version of TDF that yields less bone and kidney toxicity. (Several Phase I and Phase II trials of this STR have been completed.) If the STR is approved, Janssen will be responsible for all manufacturing, registration, distribution and commercialization.

"Janssen has vast experience in developing and making innovative HIV treatments available to patients and we have engaged in several successful collaborations with Gilead," Paul Stoffels, chief scientific officer at Johnson & Johnson, Janssen's parent company, said in a press release. "We are proud to be extending our collaboration and leading the development of this [Prezista]-based single-tablet regimen. Our ultimate goal is to offer new treatment options for people living with HIV. If approved, this STR has the potential to provide additional choice in the form of another one pill, once a day, as a new and simplified regimen."

Janssen and Gilead have also expanded a separate agreement, established in 2009, which led to the STR Complera. The companies intend to swap TAF for TDF in Complera—a move that Gilead has already made with the company's STR Stribild. (Gilead filed for U.S. Food and Drug Administration approval of the TAF-inclusive Stribild in November.) Gilead will be responsible for the development and commercialization of the updated Complera in most countries, with Janssen leading the commercialization in select others.

To read the press release, click here.

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